

REMARKS

The Examiner quoted the applicant's Preliminary Amendment statement that "I believe the original patent to be partly inoperative or invalid by reason of a defective specification." According to the Examiner, no amendments were made to the specification to correct these deficiencies. The Examiner is directed to the remainder of the quoted statement which states, ". . . in that I claimed less than I had a right to claim in the patent." Applicant respectfully points out that the specification includes not only the written description of the invention, but also the claims. The Examiner is directed to MPEP 608.01(b) and PTO Form paragraphs 6.01(i) and 6.02(i) Content of Specification in which the claims are identified as part of the specification. See also, Baxter Int'l v. McGaw, Inc., 149 F.3d 1321, 1333 (Fed.Cir. 1998) ("Both statute, 35 U.S.C. Section 111 and federal regulation 37 CFR 1.51 make clear the requirement that an application for a patent must include (1) a **specification (which includes both the written description and the claims)** . . ."") (emphasis added). Because several claims were amended in the Preliminary Amendment to correct the noted deficiencies in the specification, Applicant believes that the specification was in fact amended.

The Examiner indicates that Exhibits 1 through 5 were referenced within the applicant's reissue oath and declaration, but that none of those exhibits were provided with the reissue application. Although our records seem to indicate those Exhibits were included in the reissue application, additional copies of those Exhibits are attached to this Amendment A to ensure that all relevant information is provided to the Examiner.

The Examiner points to a discrepancy in the name of the assignee of the '260 patent which is the basis of this reissue application. According to the Examiner, Applicant indicated the assignee for the '260 patent was "Surgical Technologies, Inc." while the assignee as recorded on Reel: 007519, Frame: 0922 shows an assignment to "Surgical Accessories, Inc." The correct assignee of the '260 patent is Surgical Accessories, Inc. as recorded.

The Examiner indicates Applicant's Information Disclosure Statement filed on September 20, 2000 did not include the foreign patents listed on the face of the '260 patent. A Supplemental Information Disclosure Statement will be filed later to include those foreign patents and the printed publications referenced in the '260 patent.

The Examiner cites the judicially instituted doctrine called the "recapture rule" to reject all the claims in the Applicant's reissue application. However, to apply the recapture rule, there must be a definite and deliberate act on the part of the patentee to surrender subject matter to overcome a rejection based on prior art.

The recapture rule had its genesis in the United States Supreme Court case of *Leggett v. Avery*, 101 U.S. 256 (1879). In that case, the Supreme Court clearly established the basis of the recapture rule and the policy behind its origination. In Legget the Court stated:

"We think it was a manifest error of the commissioner, in the reissue, to allow to the patentee a claim for an invention different from that which was described in the surrendered letters, and which he had thus expressly disclaimed.

. . . we consider it extremely doubtful whether reissued letters can be sustained in any case where they contain claims that have once been formally disclaimed by the patentee, or rejected with his acquiescence,

and he has ***consented to such rejection in order to obtain his letters-patent.*** Under such circumstances, the rejection of the claim can in no just sense be regarded as a matter of inadvertence or mistake.

Leggett, 101 U.S. 259-60 (emphasis added).

Later cases within the Court of Appeals for the Federal circuit have found that “[t]o determine whether an applicant surrendered particular subject matter, we look to the prosecution history for arguments and changes to the claims made *in an effort to overcome a prior art rejection.*” In re Clement, 131 F.3d 1464, 1469 (Fed. Cir. 1997). (emphasis added). See also, Mentor Corp. v. Coloplast, Inc., 998 F.2d 992, 995-96 (Fed. Cir. 1993); Ball Corp. v. United States, 729 F.2d 1429, 1436, (Fed. Cir. 1984).

While, the recapture rule does not apply in the absence of evidence that the applicant's amendment was "an admission that the scope of that claim was not in fact patentable," (Seattle Box Co. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 826, (Fed. Cir. 1984), "the court may draw inferences from changes in claim scope when other reliable evidence of the patentee's intent is not available." In re Clement, 131 F.3d at 1469 (citing Ball, 729 F.2d at 1436). Although "deliberately canceling or amending a claim in an effort to overcome a reference strongly suggests that the applicant admits that the scope of the claim before the cancellation or amendment is unpatentable, . . .*it is not dispositive because other evidence in the prosecution history may indicate the contrary.*" In re Clement, 131 F.3d at 1469 (emphasis added) (citing Mentor, 998 F.2d at 995-96; Ball, 729 F.2d at 1438; Seattle Box Co., 731 F.2d at 826 (declining to apply the recapture rule in the absence of evidence that

the applicant's "amendment . . . was in any sense an admission that the scope of [the] claim was not patentable").

In this case, as stated in the Applicant's reissue oath and declaration, Applicant's attorney cancelled some original claims in the original '260 patent application, but there was no patentability basis for doing so. Applicant's attorney then added new claims when, again, there was no patentability basis for doing so. While the new claim 16 offered by my attorney during prosecution of the '260 patent still incorporated all of the individual elements disclosed by me for my invention, the claims in my original application clearly delineate the separate character of the sealing ridges from the interlocking rings by incorporating these separate structural elements into individual claims. Without any apparent basis, however, Applicant's attorney simply and erroneously combined the sealing rings and the interlocking groove into a single new claim.

There was no basis in any of the Examiner's Office Actions for my attorney to make these amendments and the amendments were not offered in response to overcome any arguments regarding patentability because new claim 16 retained all of the structural components objected to by the Examiner.

It must also be noted that while my attorney erroneously offered an improperly constructed new claim 16 in his response to the Final Office Action, Applicant's attorney nevertheless continued to offer arguments in support of the fact that the sealing rings and the interlocking mechanism of my invention were two separate and distinct elements. (See Exhibit 5, pages 4-6).

In the written description of the '260 patent application, there were two methods of retaining the liner into the shell. One method used an interlocking mechanism consisting of a locking ridge which could be made integral with the outer surface of the liner. The locking ridge could engage with an interlocking groove on the inner surface of the shell, and the engagement of the locking ridge and the interlocking groove provided one way in which the liner could be retained within the shell. A second method of locking the liner and the shell together was by the incorporation of a plurality of generally rounded peripheral tabs on the edge of the liner which engaged notches in the shell which, by means of a pair of inwardly projecting lips, grasped the tabs to retain the liner into the shell. However, despite the disclosure of these two methods in the '260 patent application, Applicant's attorney only claimed the second method of locking the liner to the shell as a separate dependant claim 6 of the '260 Patent, and failed to also claim the first method of locking the liner to the shell as another separate dependant claim. Instead, as indicated in Applicant's reissue oath and declaration, Applicant's attorney erroneously incorporated the first locking method into the fourth paragraph of independent claim 1 as a structural element of that independent claim. In doing so, claim 1 is a narrower claim than I am entitled to in light of the disclosure in my original patent application.

Finally, for unknown reasons, Applicant's attorney changed the name of the invention from "a prosthesis" to "an acetabular component." It is clear from the '260 written description that Applicant believed that his invention covered a device for use in all situations wherein a prosthesis was to be used to replace a skeletal joint in humans,

or in animals treated by veterinarians -- not just hip replacements in humans. Despite this clearly define intent to cover a broad spectrum of joint replacement procedures, Applicant's attorney revised the language of all six claims of the '260 Patent to unnecessarily limit Applicant's invention to being an "acetabular component."

From the above, the prosecution history clearly shows that the changes made by the attorney in the original patent application for the '260 patent were not made in an effort to overcome rejections based on prior art. In fact, to this day, it is unclear to the Applicant why the changes were made by his attorney.

Application of the Supreme Court's analysis in Legget and the Federal Circuit's analysis in In re Clement, Mentor Corp., Ball Corp., and Seattle Box Co., require a showing that the Applicant amended the claims in the '260 patent application to overcome a rejection based on prior art. Nothing in the prosecution history meets this requirement. Instead, the prosecution history for the '260 patent simply shows that Applicant's attorney arbitrarily and without any specific basis, simply and erroneously narrowed Applicant's claims. Therefore, absent a showing that the subject matter removed from Applicant's claims during the prosecution of the '260 patent were deliberately surrendered in an effort to overcome a rejection based upon prior art, the "recapture" rule is not applicable to Applicant's reissue application for the '260 patent and the rejection of Applicant's reissue claims should be withdrawn.

The Examiner also rejects claims 1-5, and 7-11 under 35 U.S.C. 112 as being indefinite because "acetabular" in claim 1, line 6, and "said tabs" in claim 10, lack antecedent basis. Claim 1 is amended herein to delete the word "acetabular" from line

6. Claim 10 is amended herein to change the words "said tabs" to "a plurality of generally rounded peripheral tabs on the peripheral edge of said liner."

The Examiner rejects claims 1-7, 9, and 12 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,314,487 issued to Schryver et al. The Examiner indicates that Schryver discloses a prosthesis comprising a shell 14 having a smooth inner sealing surface 19, and a "liner" as shown in FIG. 9 of that patent which includes at least one circumferential peripheral annular seal 40, said engaging seal and smooth sealing surface existing to restrict migration of debris between the interface of the shell and liner. Applicant points out that item 19 of Schryver is identified as a "bore wall" (col. 5, line 20; col. 5, line 30; col. 5, line 45; and col. 5, line 54-55) and refers to what appears to be a countersunk surface in one end of the plurality of openings 18 which exist in the shell 14. As disclosed in Schryver, the purpose of the bores 18 and the bore walls 19 are to "function as drill guides for the surgeon." (col. 5, lines 21-22 and col. 5, lines 29-34), and to provide a method to attach the pegs 25-29 to the shell 14 (col. 5, lines 35-48). As such, the bore walls 19 bear no configurative or functional resemblance to the smooth inner sealing surface 38 of the shell 32 as disclosed in the '260 patent, and thus these elements of the '260 patent are not anticipated by Schryver.

Additionally, the "liner" in FIG. 9 of Schryver is in fact not a liner at all but, is instead one of the several embodiment of the pegs 25B used "to provide a rigid anchor for the cup 14." (col. 5, lines 40-41). The Examiner indicates that the circumferential peripheral seal 40 shown in FIG. 19 is to restrict the migrations of debris between the interface of the shell and the liner. However, as an introduction to the various peg

embodiments, one of which is shown in FIG. 19, Schryver states, "various embodiments of the pegs; their respective attachments to the cup 14 are illustrated." (col. 5, lines 47-48). Thus, Schryver does not disclose the use of circumferential peripheral annular seal 40 to prevent the migration of debris between the shell and the liner, but instead to only affix the pegs 25B to the cup 14. Clearly, fixation of the pegs to the shell does not require that the fixation provide a seal against the entrance of debris, and Schryver does not teach that purpose.

The Examiner also points to FIG. 2 of Schryver as examples of the circumferential groove and peripheral notch elements of the '260 patent. However, as shown in FIG. 22 of Schryver, the interface between the annular surfaces 114 and 155 with the annular surfaces 110 and 111 does not function in the manner of the circumferential grooves and notches of the '260 patent. Schryver discloses an interference fit between "the annular corrugated shoulder 108" and liner 72. (col. 8, lines 31-52). This is a distinctly different mechanical arrangement than the use in the '260 patent requiring a series of angular notches on the shell 32 which grasp the generally rounded tabs 60 on the liner 42. This mechanical distinction clearly distinguishes Schryver from the '260 patent.

Therefore, from the above, Applicant respectfully contends that Schryver does not disclose each and every one of the elements of claims 1-7, 9, and 12 of the reissue application and that the present invention is not anticipated by Schryver.

The Examiner also rejects claims 1-5 and 7-12 under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Patent No. 4,650,491 issued to Parchinski in view of

U.S. Patent No. 5,480,448 issued to *Mikhail*. According to the Examiner, *Parchinski* teaches a prosthesis comprising a shell 12 having a smooth inner sealing surface 22 (FIG. 5) and a liner 14 including at least one circumferential peripheral annular seal 40, said seal engaging said smooth sealing surface to restrict migration of debris between the interface of the shell and liner. The Examiner notes that *Parchinski* fails to utilize at least one screw hole, but also notes that *Mikhail* teaches that it is well known in the art to utilize at least one screw hole in the prosthesis shell. The Examiner also points to item 129 and 30 of *Parchinski* to reject claim 9; to Figures 13-15 of *Mikhail* to reject claim 10; and to the rounded tab in *Parchinski* to reject claim 11. Finally, the Examiner also rejects claims 7, 9, 10, and 11 as containing elements previously disclosed in *Mikhail* and *Parchinski*.

In order to establish a *prima facie* case of obviousness, the prior art teachings must be sufficient to suggest making the substitution or modification necessary to make the claimed invention, to one of ordinary skill in the art in the absence of appellant's own disclosure. In re Lalu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984); In re Laskowski, 871 F.2d 115, 117, 10 USPQ2d 1397, 1398-99 (Fed. Cir. 1989); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). The motivation to make a specific structure "is not abstract, but practical, and is always related to the properties or uses one skilled in the art would expect the [structure] to have, if made." In re Gyurik, 596 F.2d 1012, 1018, 201 USPQ 552, 557 9CCPA 1979). See also, Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1556, 225 USPQ 26, 31 (Fed. Cir. 1985) ("critical inquiry is whether there is something in the

prior art as a whole to suggest the desirability, and, thus, the obviousness, of making the combination.”).

There also must have been a reason apparent at the time the invention was made to a person of ordinary skill in the art for applying the teaching at hand, in the manner proposed or the use of the teaching as evidence of obviousness will entail prohibited hindsight. Graham v. John Deere Co., 86 S.Ct. 684, 383 U.S. 1, 148 USPQ 459 (1966) and In re Nomiya, 509 F.2d 566, 184 USPQ 607 (CCPA 1975).

In view of the above law regarding 35 U.S.C. 103, Applicant respectfully suggests that the combination of *Parchinski* and *Mikhail* do not meet the requirements to establish a prima facie case of obviousness sufficient to reject claims 1-5 and 7-12 of the present reissue application.

Regarding the Examiner’s rejection of claims 1-5, the Examiner points to the shell 12 of *Parchinski* as providing a smooth inner sealing surface 22. However, FIG. 3 of *Parchinski* clearly shows the shell 12 as being a ring having an opening 26 at the bottom of the shell which allows the liner to be completely exposed to the bone structure of the patient. Additionally, *Parchinski* specifically teaches the existence of the opening in the shell 12 by stating “. . . the polar region of shell 12 being removed to provide a large circular opening 26 for allowing visual assessment of bone apposition during insertion of shell 12 into the acetabulum.” (col. 2, lines 44-47). Therefore, *Parchinski* teaches away from using a shell which provides a sealing surface, because the shell 12 of *Parchinski* requires a large opening in the bottom of the shell thereby completely excluding the possibility that the shell 12 can have a smooth inner sealing

surface. From this, it is clear that *Parchinski* does not teach the same inner shell as claimed by the present invention and thus does not make claims 1-5 obvious.

It should also be noted that nothing in either *Parchinski* or *Mikhail* teaches the use of their inventions to provide a prosthesis with an interlocking seal to prevent the migration of debris into the interface between the liner and the shell. Additionally, due to the configuration of the components of both *Parchinski* and *Mikhail*, neither of those inventions have the inherent property of providing a seal between the liner and the shell. Thus, while *Parchinski* and *Mikhail* appear to have similar elements as the present invention, the elements referenced by the Examiner are functionally distinct from the elements of the present invention, and neither *Parchinski* nor *Mikhail* teach or suggest that the shell and the liner should have a sealing connection. Therefore, Applicant respectfully suggest that *Parchinski* and *Mikhail* do not form a proper basis for rejecting claims 1-5 as being obvious under 35 U.S.C. 103(a).

Regarding the Examiner's rejection of claim 10, Figures 13-15 do not disclose "a pair of inwardly projecting lips to grasp said tabs as they engage." Instead, *Mikhail* discloses "a series of sawtooth members 257 extending around the shell interior 220 in a position to be engaged by the sawtooth members 250 of the acetabular cup member 212." (Col. 5, lines 58-61). *Mikhail* teaches no other engagements means similar to the method claimed in reissue claim 10 of the '260 patent. Thus, *Mikhail* does not reveal the grasping elements of claim 10.

Claim 9 of the present reissue application requires "a plurality of peripheral notches" formed within the shell. The Examiner points to elements 129' of *Mikhail* and

30 of *Parchinski* as being identical to the peripheral notches of claim 9. However, *Mikhail* and *Parchinski* use these notches for alignment purposes only, with the liner not being secured to the shell, and the liner being removable from the shell without resistance, by simply moving the liner axially away from the shell. In the present invention, the peripheral notches are configured and located to be used primarily to secure the liner to the shell. Once assembled, the notches in the present invention secure the liner to the shell and provide a resistance to the removal of the liner from the shell if the liner is moved axially in relation to the shell. Thus, the notches in claim 9 are functionally different from the notches in both *Parchinski* and *Mikhail*. Claim 9 is amended herein to indicate the notches in the present invention as being securement notches.

The Examiner also points to the single element 48 of *Parchinski* as being the same as the generally rounded tabs 60 of the '260 patent, and that it would have been obvious to duplicate the number of elements 48 to utilize more than one tab. However, *Parchinski* teaches the semicylindrical projection 48 as being an alignment tab to prevent "gross rotational movement between insert 14 and shell12." (col. 3, lines 30-31). The generally rounded tabs of claim 11 in the present invention are configured and located primarily for the purpose of securing the liner to the shell. Claim 11 is amended herein to indicate the tabs in the present invention are securement tabs.

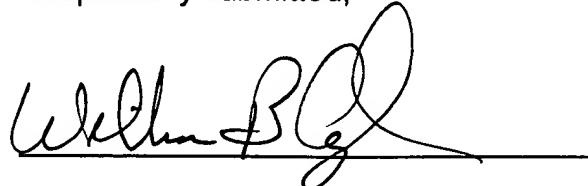
The Examiner points to elements 28 and 38 of *Parchinski* as being the same as the interlocking circumferential groove of claim 7. However, the function of the groove in claim 7 is quite different than elements 28 and 38 of *Parchinski*. *Parchinski* discloses

the use of elements 28 and 38 to insure "a positive resistance to axial movement or chatter of insert 14 within shell 12" and to insure "positive resistance to rotational chatter of insert 14 within shell 12." (col. 3, lines 10-17). In contrast, it is a primary object of the present invention to provide a seal to prevent the migration of debris into the area between the liner and the shell. (See the '260 patent, col. 4, lines 27-29). Thus, there is a distinct functional difference between elements 28 and 38 of *Parchinski*, and the interlocking circumferential groove 54 of the present invention. Claim 7 in the present application is amended herein to indicate the sealing characteristic of the interlocking circumferential seal.

Thus, regarding the Examiner's rejection of claims 1-5 and 7-12 under 35 U.S.C. 103(a), Applicant respectfully contends that either alone, or in combination, *Parchinski* and *Mikhail* do not form a proper basis to reject those claims as being obvious.

Inasmuch as each of the rejections have been overcome by the amendments or by traverse, it is respectfully requested that the rejections of 1-5 and 7-12 be withdrawn, and favorable consideration and a notice of allowability of claims 1-5 and 7-12 are respectfully solicited.

Respectfully submitted,



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SERIAL NO.: 09/595,352
FILED: June 15, 2000
EXAMINER: Bruce E. Snow
DOCKET NO.: WBC 7403US
GROUP ART UNIT: 3738
FOR: Acetabular Component With Improved Liner Seal and Lock

**AMENDMENT
VERSIONS WITH MARKINGS
TO SHOW CHANGES MADE**

IN THE CLAIMS:

1. (Twice amended) A prosthesis comprising:

a shell, said shell including at least one screw hole formed therein,

said shell including a smooth inner sealing surface; and

a liner configured to seat within said [acetabular] shell, said liner

including at least one circumferential peripheral annular seal, said

at least one peripheral seal engaging said smooth inner sealing

surface of said shell in a sealing engagement to restrict migration

of debris toward said at least one screw hole.

7. (Amended) The prosthesis of claim 1 wherein said shell also has at least one securing interlocking circumferential groove.

9. (Amended) The prosthesis of claim 1 wherein said shell also has a plurality of securing peripheral notches formed therein.

10. (Amended) The prosthesis of claim 9 wherein each notch includes a pair of inwardly projecting lips to grasp a plurality of generally rounded peripheral tabs on the peripheral edge of said liner as they engage.